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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,797	10/15/2001	Jeffry D. Watkins	AME-06805	3451

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,797

Applicant(s)

WATKINS ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 6-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 6-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

Claims 1 and 6-24 are pending and under examination.

Claims 2-5 have been cancelled

Withdrawn Objection

Specification

The objection to the abstract of the disclosure has been withdrawn in view of the amendments to the abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 6-24, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Yelton et al (EP 699,756) in view of Huse for reasons of record, or Yelton in view of either Osbourn et al (6,342,588) or Winter et al (US 6,291,158 B1).

Response to Arguments

Applicants argue that Yelton does not teach creation of an antibody library comprising about 10^4 or more of different binding molecule species as presently recited in claim 1 (a)(ii). It is further argued that the BR96 mutations were merely generated by deletion/stop templates. The codon-based oligonucleotides were synthesized with 50% bias for the parent BR96 CDR sequences.

In reply, attention is directed to the Huse reference cited by Yelton (copy of the Huse reference was provided to applicants in the last Office action on 11/16/04). Huse discloses at e.g., page 3914, col. 1 that very large combinatorial libraries of 10^5 - 10^8 distinct antibody has been generated from simple organism, as bacteriophage. The use of bacteriophage facilitated the production and manipulation of antibody fragments, increasingly aiding the search for useful antibodies, unlike the slow growth rates and difficulty of producing mab in mammalian cells.

Applicants' further arguments as to the generation of BR96 mutations is irrelevant as Yelton discloses nearly the same process steps except for the new added limitation i.e., size of the library.

Accordingly, the Yelton reference renders the claimed prima facie obvious.

Yelton discloses at page 19, line 11 up to page 20, line 7, a method of contacting nitrocellulose filters (solid support, as claim) blocked with a blocking buffer (page 26, lines 22-26) to prevent nonspecific binding of antibodies and coated with goat anti-human kappa light chain conjugated to alkaline phosphatase. And then contacted with phage BR antibody library. See further the cited Huse reference, (J.Immunol.) which describes the coating of support. Also, page 16, lines 5-50; page 24, lines 35-40. Yelton discloses at page 21, line 54 that the method further comprises binding the above BR96 with tumor cell line, H3396. See further all the examples, specifically Example 5 at page 32.

Yelton does not disclose the library as comprising of 104 or more of different binding molecule species, as presently claimed. However, Winter at col. 1, line 15 up to col. 2, line 20 discloses a library that contains at least about 105 different VH. This library size mimics the immune system of mammals of 107. This large portion enables screening a larger portion of immunological repertoire for receptors that overcome the deficiencies of the traditional hybridoma technique. Osbourne basically discloses the same library size as Winter, at col. 23, lines 1-4. See further col. 3 up to col. 8. Like, Winter, Osbourne discloses the advantages of having a large

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diverse library. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make a library size of 104, as claimed, in the method of Yelton as taught by either Winter or Osbourne. The advantages taught by Winter or Osbourne would provide the motivation to one having ordinary skill in the art at the time the invention was made. It is further well known in the art that library of this size is conventionally produced as most desirable for screening purposes.

Claims 1, 6 and 18-19, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowman et al (USP 6,172,213) for reasons stated in the last Office action and reiterated below.

Lowman et al discloses at col. 72, Example 4, a method of contacting a phage F(ab) libraries with a solid support coated human IgE. The phage libraries were constructed by fusing to the C-terminal domain of bacteriophage M13g3p by known techniques. The presence of an amber codon between the heavy-chain antibody domain and the g3p domain on phage permits the expression of the phage-displayed fusion protein only in amber suppressor strains of E. coli, while soluble F(ab) protein can be obtained with this same construct in non-suppressor strains of E. coli. For affinity-selections of phage particles displaying F(ab)

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variants, phage was prepared by sodium chloride/polyethylene glycol precipitation from E. coli culture supernatants. 96-well plastic plates were coated with IgE (human IgE). The IgE solution was then removed, and the plates were incubated with a blocking solution of horse serum. At col. 75, line 45 up to 76, line 43 an assay with an antigen i.e., IgE binding of the phage is discussed. Lowman discloses at col. 58, Example 1 up to col. 60, line 17 a method comprising coating test plates with rat anti-mouse IgG in sodium carbonate buffer, then blocked with bovine serum albumin in phosphate buffered saline. Accordingly, the method steps of Lowman render prima facie obvious the instant claimed method.

Response to Arguments

Applicants argue as applied to the amended claims that claim 1 does not elute the antibody bound solid support as it uses this complex to further capture antigen(s) in a sample.

In response, with applicants' used of the word comprising, elution step of the antibody from the bound complex to identify one or more antigens contained in the antibody-antigen complexes is not precluded. It has been long held that the use of the term "comprising" leaves a claim open for inclusion of steps other than those recited in the claims". *Ex parte Davis*, 80 USPQ 448.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Bailey et al discloses *S. aureus* genes and polypeptides.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

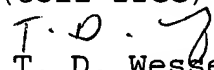
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

August 3, 2005